

COVID-19 Vaccine Update

January 7, 2021

Tested, safe and effective COVID-19 vaccines will help us get back in control of our lives and back to the people and places we love.

Scientists had a head start. The vaccines were built upon decades of work to develop vaccines for similar viruses.

Tested, safe and effective. More than 70,000 people volunteered in clinical trials for two vaccines (Pfizer and Moderna) to see if they are safe and work to prevent COVID-19 illness. Volunteers included Black/African Americans, Hispanics/Latinx, Asians and others. To date, the vaccines are 95% effective in preventing COVID-19 with no serious safety concerns noted in the clinical trials. The U.S. Food and Drug Administration (FDA) makes sure the vaccines are safe and can prevent people from getting COVID-19. Like all drugs, vaccine safety continues to be monitored after they are in use.

You cannot get COVID-19 from the vaccine. You may have temporary reactions like a sore arm, headache or feeling tired and achy for a day or two after receiving the vaccine.

Supplies are very limited. Right now, very few vaccine doses are available.

Take your shot at no cost. The COVID-19 vaccine will be available for free, whether or not you have insurance.

VACCINE SAFETY

Are there vaccines that are safe and work in preventing COVID-19?

Yes. Two vaccines from Pfizer-BioNTech and Moderna have proven to prevent COVID-19 illness with no safety concerns in the clinical trials. They are 95% effective.

Who makes sure the vaccines are safe and can prevent COVID-19?

The U.S. Food and Drug Administration (FDA) makes sure all food and drugs are safe. The COVID-19 vaccines must pass clinical trials like other drugs and vaccines. The FDA checks the work and authorizes vaccines only if they are safe and effective. The FDA can get them to people faster through an Emergency Use Authorization. Like all vaccines, the FDA keeps checking safety through the <u>Vaccine Adverse Events Reporting System (VAERS)</u>. Health care providers are required to report serious side effects, or if someone gets seriously ill with COVID-19. There is also a smartphone-based health checker called <u>V-SAFE</u> that uses text messaging and web surveys to do health check-ins after people receive a COVID-19 vaccination. People can report any problems they may have with a vaccine through V-SAFE.

VACCINE DEVELOPMENT AND AUTHORIZATION

What is an Emergency Use Authorization (EUA)?

An Emergency Use Authorization (EUA) allows the FDA to get a safe COVID-19 vaccine to you quickly during a public health emergency. An independent advisory committee makes sure the vaccines are safe and work before issuing an EUA.

• Pfizer applied for an EUA on November 20, 2020, the advisory committee recommended authorization on December 10, 2020, and the <u>EUA</u> was approved on December 11, 2020.

 Moderna applied for an EUA on November 30, 2020, the advisory committee recommended authorization on December 17, 2020, and the EUA was approved on December 18, 2020.

What happens after an EUA is issued?

The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) decides who should be vaccinated to make sure the vaccine is safe and works for those who get it.

How do the Pfizer and Moderna vaccines work?

You cannot get COVID-19 from the vaccine. The Pfizer and Moderna vaccines give your body instructions to make a kind of protein. This protein safely teaches your body to think the virus is attacking. Your body then strengthens itself to fight off the real COVID-19 if it ever tries to attack you. Your body gets rid of the small protein naturally and quickly.

What are the differences between the Pfizer and Moderna vaccines?

The Pfizer and Moderna vaccines work the same way to prevent people from getting COVID-19. In addition, both vaccines require two doses. And both are very effective in preventing someone from getting COVID-19 and had no serious safety concerns noted in the clinical trials.

The vaccines are stored differently. The Moderna vaccine does not need to be stored as cold as the Pfizer vaccine, so more providers will be able to easily use it. While both vaccines require two doses, the time between doses is different. The Moderna vaccine doses are given 4 weeks apart. The Pfizer vaccine doses are given 3 weeks apart. Who can get the vaccine is also different. The Moderna vaccine is authorized for adults aged 18 and older. The Pfizer vaccine is authorized for people aged 16 and older.

The temporary reactions are similar for both vaccines. Temporary reactions may include a sore arm, headache and feeling tired and achy for a day or two after receiving the vaccine. More people who were in the Moderna clinical trial experienced these temporary reactions. The reactions are more common after the second dose than the first dose. Younger people are more likely to have reactions than older people. Neither vaccine can give you COVID-19.

Will the vaccine work against new variants of the COVID-19 virus?

All viruses change over time. The changes (or variants) are expected. At this time, there is no evidence that any new virus variant of COVID-19 in the U.S. or other countries will change how effective the COVID-19 vaccine is. Scientists are working to learn more about new variants.

How can someone enroll in a clinical trial for a vaccine?

Over 100 vaccines for COVID-19 are under development and many are in clinical trials that are recruiting participants. People interested in enrolling in a COVID-19 vaccine trial may visit the following website: https://www.coronaviruspreventionnetwork.org/clinical-study-locations/.

VACCINE SHIPPING AND STORAGE

How many vaccines will the state receive?

States will receive very limited supplies at first. The federal government decides how many COVID-19 vaccines each state gets based on the state's population of people aged 18 and up.

How will the vaccine be shipped?

The federal government ships the vaccines and vaccination supply kits to states each week. NC DHHS then determines which vaccine providers will receive vaccine doses based on their ability to reach prioritized populations. The manufacturer (Pfizer or Moderna) ships the vaccines and vaccination supply kits to the local vaccine providers in North Carolina.

How will the vaccine be stored?

North Carolina is working closely with providers to safely store vaccines that need ultra-cold storage or frozen storage. Vaccines that need ultra-cold storage will come with packaging and cooling material for places that do not have permanent ultra-cold storage. The Moderna vaccine does not need ultra-cold storage. The state, the manufacturer and CDC will deliver training on COVID-19 vaccine storage, handling and administration.

GETTING VACCINATED

Who will be vaccinated first?

To save lives and slow the spread of COVID-19, independent state and federal public health advisory committees recommend first protecting health care workers caring for patients with COVID-19, people who are at the highest risk of being hospitalized or dying and those at high risk of exposure to COVID-19. The first supply will go to vaccinate health care workers working with COVID-19 patients, like doctors, nurses and those cleaning areas used by COVID-19 patients. Hospitals will give vaccines to staff on different days in case they have temporary reactions that may prevent them from working for a day or two.

Long-term care staff and residents are also one of the first groups who will receive a vaccine. Most vaccinations at nursing homes, adult care homes and other long-term care settings are being managed by the federal government. However, the vaccines used in long-term care will come from North Carolina's supply.

COVID-19 vaccinations are now available to people 75 and older. Because vaccine supplies are still limited, those 75 and over may have to wait, but they have one of the first spots to take their shot.

As more vaccines become available, vaccinations will be offered to everyone who wants one, including in clinics and drug stores, as well as at vaccination events in communities.

How will people know if they are in the first Phase (1a) of vaccinations?

Phase 1a vaccines will first go to health care workers critical to caring for patients with COVID-19 or at high risk for COVID-19 exposure because of their work duties. That includes people:

- caring for patients with COVID-19;
- working directly in areas where patients with COVID-19 are cared for, including staff responsible for cleaning, providing food service and maintenance in those areas;
- performing procedures at high risk of aerosolization on patients with COVID-19 (e.g., intubation, bronchoscopy, suctioning, invasive dental procedures, invasive specimen collection, CPR); and,
- handling decedents with COVID-19.

Health care workers administering vaccines in initial mass vaccination clinics are part of this first phase. All long-term care staff and residents qualify for Phase 1a. Vaccines in most long-term care facilities are being managed by the federal government through the newly created Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens.

Learn more about Phase 1a.

Are outpatient providers included in the first Phase (1a) of vaccinations?

Outpatient providers who have an increased risk of exposure beyond that of a typical general outpatient setting should be included in the Phase 1a. This could include outpatient providers who are focused on COVID-19 patient

evaluation, respiratory care (e.g., respiratory diagnostic testing centers), members of a dedicated respiratory care team or those frequently involved in COVID-19 testing sites. Outpatient dentists or dental hygienists are included in Phase 1a if they meet the above criteria for outpatient providers. Local health departments, health care employers, hospitals and health systems all play a role in vaccinating health care workers in Phase 1a.

Who is part of the vaccination Phase (1b)?

There are not enough vaccines for everyone in this phase to be vaccinated at the same time. Vaccinations will be available to groups in the following order.

- Group 1: Persons 75 years and older: All people age 75 and older will be eligible to be vaccinated first in this group. There is no requirement to have certain qualifying chronic conditions.
- Group 2: Health care workers with in-person patient contact and frontline essential workers 50 years
 or older. Patient-facing direct health care workers are those directly caring for or working directly in areas
 where in-person patient care occurs. Essential frontline workers are defined by the CDC as workers who are
 in sectors essential to the functioning of society and who are substantially higher risk for exposure to
 COVID-19. There is no requirement to have certain qualifying chronic conditions.
- Group 3: All other health care workers with in-person patient contact and frontline essential workers of any age. There is no requirement to have certain qualifying chronic conditions.

Detailed information about who is included in Phase 1b is outlined in the Deeper Dive Phase 1b Fact Sheet.

Which chronic conditions put someone at increased risk for severe illness from COVID-19, making them a higher priority for vaccination?

The CDC defines the chronic medical conditions that put someone at higher risk of severe illness from COVID-19. Currently, the list includes cancer, chronic kidney disease, COPD (chronic obstructive pulmonary disease), heart conditions (heart failure, coronary artery disease, cardiomyopathies), immunocompromised state (weakened immune system) from solid organ transplant, pregnancy, sickle cell disease, smoking and type 2 diabetes mellitus. This list of conditions may be updated by the CDC and can be found here.

How is North Carolina promoting equity in its vaccination plan?

NCDHHS has a specific focus on building trust with historically marginalized populations. Longstanding and continuing racial and ethnic injustices in our health care system contribute to lack of trust in vaccines. The department is partnering with trusted leaders and organizations to provide accurate information about COVID-19 vaccines to all North Carolinians and ensure equitable access to vaccines.

It is the responsibility of all vaccine providers to ensure equitable access to vaccines. This will mean taking intentional actions to reach and engage historically marginalized communities, such as partnering with providers who serve such communities to make the vaccine more accessible.

GETTING VACCINATED

How will I know when it's my turn to get a vaccine?

The best way to fight COVID-19 is to start first with vaccines aimed at helping to slow the spread and save lives. YourSpotYourShot.nc.gov is updated regularly with information about who can currently get vaccinated. Talk with your health care provider or employer about where your spot is based on your health and job status. How quickly North Carolina moves through each phase will depend on the available vaccine supply. Currently, supplies are very limited. The federal government notifies states weekly of how much vaccine they will receive. We find out the week before how many doses of each vaccine we will receive for the following week. This makes it difficult to know when we will move to the next phase.

Where will I be able to get vaccinated?

Currently, supplies are very limited. Right now, very few vaccine doses are available. If it is your turn, your local health department or hospital can help you get your shot. Because supplies are very limited, most doctors cannot provide vaccinations in their offices.

As vaccines become more widely available, vaccinations will be offered to everyone who wants one in clinics and pharmacies, as well as vaccination events in communities. We will continue to expand the available sites so that people have a spot where they can easily get their vaccine. Information on where to take your shot against COVID-19 is available at YourSpotYourShot.nc.gov.

When it's your turn, you can get your shot from any local health department in the state, no matter where you live.

Do I need to sign up to get vaccinated?

For people in the first group (Phase 1a), your health care employer, local health department or long-term care facility will register you for the vaccine. You should follow the instructions they give to you. At this time, you may be registered through your employer for Phase 1a. You can also schedule at a site providing vaccinations to get registered when it is your turn in the prioritization groups. Learn how to find your spot to get your shot at https://covid19.ncdhhs.gov/findyourspot.

Will I need to sign a consent form to get vaccinated?

You can provide verbal consent. Written consent is not generally required, but some providers may require or request written consent.

Does the state require or mandate vaccination?

No. North Carolina has no plan to require people to be vaccinated against COVID-19. It is possible that some employers or schools will require vaccines for their employees or students.

What kind of identification will be required to be vaccinated?

North Carolina does not require an identification card, like a driver's license, to be vaccinated. Some employers or health care providers could request ID, but it is not required by the state.

How much will the vaccines cost?

There is no cost. They are free to everyone, even if you don't have health insurance. The federal government is covering the cost. Administration fees will also be covered for those who are uninsured and should be covered by all health insurance companies.

Are there side effects from the vaccines?

No serious side effects were reported in clinical trials. Temporary reactions after receiving the vaccine may include a sore arm, headache or feeling tired and achy for a day or two. These temporary reactions were more common after the second vaccine dose. You can take medicines like Tylenol or ibuprofen to help with these temporary reactions. While extremely rare, there have been a few cases of severe allergic reaction to the Pfizer vaccine outside of the clinical trials, and vaccine providers are prepared with medicines if they need to treat these rare allergic reactions.

What is the risk of an allergic reaction from the vaccine?

People who have had severe allergic reactions, also called anaphylaxis, to any ingredient in the <u>Pfizer</u> and <u>Moderna</u> vaccines should not receive that vaccine. People who have had this type of severe allergic reaction to any vaccine or treatment that is injected should talk with their health care provider about the risks and benefits of vaccination. People with allergies to foods, animals, environmental triggers (such as pollen), latex or medications taken by mouth, or who have family members with past severe allergic reactions, can be vaccinated with the Pfizer or Moderna vaccines. Severe allergic reactions to the vaccines have been <u>very rare</u> and mostly occurred in people who have had previous severe allergic reactions.

Vaccine providers will watch patients for 15-30 minutes after vaccination to ensure the patient's safety. Additional information can be found here for the Pfizer and Moderna vaccines.

How do I report an adverse reaction caused by the COVID-19 vaccine?

CDC and FDA encourage the public to report possible side effects (called adverse events) to the <u>Vaccine Adverse</u> <u>Event Reporting System (VAERS)</u>. This national system collects data to look for adverse events that are unexpected, appear to happen more often than expected or have unusual patterns of occurrence. Reports to VAERS help CDC monitor the safety of vaccines. Safety is a top priority.

CDC is also implementing a new smartphone-based tool called <u>v-safe</u> to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a v-safe information sheet telling you how to enroll in v-safe. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

Why are two vaccine shots necessary?

The Pfizer and Moderna vaccines require two shots a set number of days apart. You need two doses to build up strong immunity against COVID-19. The second shot will come about 3-4 weeks after the first. It is important to get two doses of the same vaccine.

While other countries may take a different approach to vaccinations, the FDA and CDC continue to recommend that everyone get two shots. Currently there is not enough data to suggest that one shot offers enough protection against COVID-19. With two shots, both the Pfizer and Moderna vaccine are 95% effective in preventing COVID-19.

If two shots are necessary, how will people know when to get their second shot?

North Carolina will use a secure data system called the COVID-19 Vaccine Management System (CVMS) to make sure you are safe and get your second shot at the right time. When a person gets the first shot, they get information on when to come back for the second and they are asked to make a second appointment. People will also be given a card with information about which vaccine they got for their first dose and the date of that shot. Keep the card in a safe spot and take a picture of it just in case it gets misplaced. People will receive an email notification with a reminder for the second shot. Individuals who choose to use V-SAFE, a CDC tool to provide personalized health check-ins after their shot, will receive text reminders for their second dose. The provider who gave the vaccine may also help with reminders for the second shot. State and federal privacy laws make sure none of your private information will be shared. The shot you take and when you need the second is confidential health information that is carefully managed to protect your privacy.

Will people who have been vaccinated still need to wear a mask and avoid close contact with others?

Yes. Everyone should continue using the 3 Ws—wearing a mask, waiting 6 feet apart, washing your hands and limiting gatherings—until most people are vaccinated. Receiving the COVID-19 shot and following the 3 Ws is everyone's best protection from getting and spreading COVID-19.

Will people who have been vaccinated still need to be guarantined?

Experts are still deciding on whether people who are vaccinated need to be quarantined if they have been in close contact with someone who has COVID-19. At this time, anyone who has been in close contact with someone who has COVID-19, besides people who have had COVID-19 in the past 3 months, should quarantine.

For how long will the vaccine protect me from COVID-19?

Since the Pfizer and Moderna trials just ended, we know that the vaccines can protect people from COVID-19 illness for at least two months. We'll know even more about how long the immunity from the vaccines lasts as people have been vaccinated for a longer period of time.

What can I do to protect myself from COVID-19 while I am waiting to be vaccinated?

North Carolinians should continue to practice the 3Ws—wear a mask, wait 6 feet apart and wash your hands—while they wait to get vaccinated and after they have been vaccinated to continue to slow the spread of COVID-19.

Why do I need to get a vaccine if I can practice other things like social distancing to prevent the COVID-19 virus from spreading?

Vaccines work to prepare your body to fight the virus if you are exposed to it. Other steps, like the 3Ws—wear a mask, wait 6 feet apart and wash your hands—help reduce your chance of being exposed to the virus or spreading it to others. Getting the COVID-19 vaccine and following the 3Ws is everyone's best protection from getting and spreading COVID-19.

GETTING VACCINATED

Are children able to get the vaccine?

Children will not receive vaccines until clinical trials are completed to ensure the vaccines are safe and work to prevent COVID-19 illness in children. The Pfizer vaccine can be given to teenagers aged 16 and up, and they are doing additional studies with children aged 12 and over.

How will staff and residents in long-term care facilities be vaccinated?

The federal government manages most vaccinations for staff and residents of long-term care facilities. Long-term care facilities include skilled nursing facilities and adult care homes. The federal government has created the Pharmacy Partnership for Long-Term Care Program with CVS and Walgreens to work with long-term care facilities to give vaccinations. They are currently vaccinating staff and residents.

Should pregnant women be vaccinated?

Pregnant and breastfeeding women may choose to receive the Pfizer or Moderna COVID-19 vaccines. Pregnant women can talk with their doctors before making the choice. You do not need to take a pregnancy test before you

get your vaccine. Women who are breastfeeding may also choose to get vaccinated. The vaccine is not thought to be a risk to a baby who is breastfeeding. Additional information can be found here for the Pfizer and Moderna vaccines.

Do people who have had COVID-19 still need to be vaccinated?

Yes. The vaccine works to protect you against a future infection. You don't need a COVID-19 test before vaccination. It is safe to get vaccinated with the Pfizer or Moderna vaccine if you have been infected in the past. Additional information can be found here for the Pfizer and Moderna vaccines.

VACCINE DATA

How will the state know who has been vaccinated?

North Carolina will use the COVID-19 Vaccine Management System (CVMS), a free, secure, web-based system accessible to all providers who give COVID-19 vaccinations. It helps vaccine providers know who has been vaccinated and with which vaccine to make sure people get the second dose of the same vaccine at the right time. It also allows the state to manage vaccine supply. Pharmacies, such as CVS and Walgreens doing vaccinations in long-term care facilities, will not use CVMS to give and manage vaccines. These pharmacies will use their own systems.

What data is the state collecting and how will it be shared?

Information about your COVID-19 vaccination is carefully managed to protect your privacy. Your immunization information will not be shared except in accordance with state and federal law. NC CVMS is a system that enables the collection of immunization information for health and safety reasons. The immunization information collected for NC CVMS is similar to the information that is required when you go to the doctor's office or a pharmacy for a vaccination, including your name, address, date of birth, location where vaccine was given, when the vaccine was given, person who administered the vaccine, information about the specific vaccine vial (expiration date, vaccine identifier number, etc.) and how the vaccine was given (e.g., in the muscle of the right arm). NC CVMS also collects information about race and ethnicity, which is necessary to support efforts for equitable vaccine distribution in NC. To meet federal requirements established by the U.S. Centers for Disease Control and Prevention (CDC) and in accordance with NC state law, NC is currently submitting the vaccine recipient's year of birth (not date of birth), the first three digits of the vaccine recipient's zip code of residence (if the underlying population in that zip code includes more than 20,000 people) and the date of submission of the vaccination record. More information about federal CDC data requirements is available at: https://www.cdc.gov/vaccines/covid-19/reporting/requirements/index.html.

What data about vaccinations will be available to the public?

North Carolina has created an online public dashboard to share data on vaccinations that will be updated weekly. You can find the dashboard here.